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Guidance Document: Pest Control Products Fees and Charges Regulations

(publié aussi en français)

8 March 2017

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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1.0 Purpose and General Information Contacts

This document provides guidance on the fees payable in Canada for the review of applications for pest control products and for the annual charge in respect of registered pest control products as detailed in the *Pest Control Products Fees and Charges Regulations (Fees and Charges Regulations)*.

Note: The *Fees and Charges Regulations* and this Fee Guidance document supersede all fee information in all prior Pest Management Regulatory Agency (PMRA) published documents.

- For general information on the regulation of pest control products or questions related to specific applications, please contact the Pest Management Information Service Toll Free at 1-800-267-6315 or outside Canada 1-613-736-3799.
- For questions regarding your invoice or your account balance, contact the PMRA Accounts Receivable Unit at:

Phone: (613)-736-3530 or Toll Free at 1-800-267-6315

Fax: (613)-736-3620

E-mail: pmra.receivable-receivable.arla@hc-sc.gc.ca

Please have your invoice number available when contacting the PMRA's Accounts Receivable Unit.

The fee form (form 6011) is available on Health Canada's website or by calling the Pest Management Information Service.

2.0 Fee Exemptions

The following applications are exempt from some or all application fees:

- i) Proposals for user requested minor use label expansion (URMULE) prepared by sponsors and submitted to the PMRA. If the proposed minor use is acceptable, the PMRA will contact the registrant of the pest control product for which the additional minor use is proposed. The registrant must then apply to amend the registered label of the pest control product, under a separate Category C application as described in the Management of Submissions Policy, which has the associated processing fee as outlined under section 3 of the *Fees and Charges Regulations* and under Section 3.2.1 of this guidance document.
- ii) A request for a foreign product use certificate under the authority of subsection 41(1) of the *Pest Control Products Regulations* is exempt from all application fees.

- iii) A request for a determination of equivalency under the grower requested own use (GROU) program as specified in section 38 of the *Pest Control Products Regulations* is exempt from all application fees.
- iv) As specified in paragraph 1(d) of the *Fees and Charges Regulations*, specific application types are exempt from all application fees specified in Schedule 1. However, these applications are subject to the processing fee as specified under section 3 of the *Fees and Charges Regulations*. The exemption applies to applications for registration and amendment to the registration of a pest control product whose active ingredient(s) is detailed in Appendix I.

Refer to Appendix I for examples of substances that may qualify for the exemption when they are the active ingredient(s) in an application.

3.0 Types of Application Fees

3.1 Scheduled Fees

3.1.1 Schedule 1

Fees for applications to register or to amend the registration of a pest control product, to which Schedule 1 of the *Fees and Charges Regulations* applies, are payable by component submitted. The fee payable is the sum of the fees for the submitted components in addition to the basic processing fee as detailed in Section 3.2.1 of this guide.

Schedule 1 fees will apply to most Category A and Category B applications as defined in the Management of Submissions Policy.

For example, Category A1.1 application to register a new technical grade of active ingredient (TGAI) and related end-use product (EP), Category A2.0 major new use applications, Category A3.2 joint review applications, applications under the data protection submission review process and Category B amendment applications.

Column 2 of Schedule 1 identifies the applicable fee depending on the application component described in Column 1. More than one component can apply to each application.

Refer to Section 4.1.1 of this guide for more information on how to calculate the total applicable fee.

3.1.2 Schedule 2

Fees for applications in respect of a pest control product that is a semiochemical or microbial agent are found in Schedule 2 of the *Fees and Charges Regulations*.

Schedule 2 fees will apply to some Category A and Category B applications, as defined in the Management of Submissions Policy, for semiochemical or microbial agents (for example, Category A1.1 application to register a new TGAI, Category A2.0 major new use application,

Category A3.2 Joint Review application and Category B or Category C amendment applications).

Note: Applications to register end-use products accompanying a Category A application for the registration of a new semiochemical or microbial TGA1 are not subject to application fees under Schedule 2. However, semiochemical and microbial pest control product applications are subject to the fee as specified under section 4, the renewal fee as specified under section 5 and any of the application types and associated fees as described in Schedule 3 of the *Fees and Charges Regulations*.

Column 2 identifies the applicable fee depending on the application type described in Column 1. Unlike Schedule 1 fees, a flat fee is charged for the application review service. The application fee payable is the highest of the fees set out in column 2.

Refer to Section 4.1.1 of this document for more information on how to calculate the applicable fee.

3.1.3 Schedule 3

Fees for other applications in respect of a pest control product are found in Schedule 3 of the *Fees and Charges Regulations*.

Applications under Schedule 3 relate to review activities associated with three (3) types of applications:

- for research authorizations and research notifications (Category E),
- to register or amend an active ingredient for the manufacture for export program (Category D1.0) and,
- to specify maximum residue limits (Category A1.3 and Category B5.0)

The type of application listed in Column 1 will determine the fee payable. The fee for a research authorization will depend on the proposed crops, active ingredient(s) or use(s). Column 2 identifies the applicable fee depending upon the application type described in Column 1. If more than one application type pertains to the application, the fee payable is the highest of the fees set out in column 2.

Refer to Section 4.1.1 of this guide for more information on how to calculate the applicable fee.

3.2 Other Fees

3.2.1 Processing Fee

Activities partially covered by this fee are being expanded to cover processing activities as well as the label review, when applicable. This includes setting-up applications within the PMRA's electronic pesticide regulatory system (e-PRS), coordination and management of applications through the review process, label and statement of product specification form reviews, fee assessments, including fee reduction requests and the preparation of decision letters and correspondence with applicants.

The processing fee applies to the following:

- Applications as described in paragraph 1(d) of the *Fees and Charges Regulations*;
- Applications subject to a Schedule 1 fee (for example, an application to register a new end-use pest control product containing a new active ingredient);
- An application in respect of a pest control product that does not include a component set out in Schedule 1, that is not of the type described in Schedules 2 or 3 and with which no further data is required to carry out the evaluation.

This fee applies to Category C applications, Category D4.0 master copy applications, Category D5.0 private label applications and emergency registration applications (Category B6.0).

3.2.2 Applications not Mentioned in the Schedules & Other Applications

As outlined in section 4 of the *Fees and Charges Regulations* applications in respect of a pest control product, other than a renewal request, that is not subject to Schedule 1, 2 or 3 fees and that do not require an evaluation are subject to this fee. This application fee will apply to notification applications (Category F).

3.2.3 Fees for Renewal Applications

As outlined under section 5 of the *Fees and Charges Regulations*, the renewal fee will apply to all applications to renew the registration of a pest control product (Category D6.0). This renewal fee is not related to the annual charge as detailed under Section 7 of this document.

Before processing a renewal PMRA will verify that there is no fee, fine, charge or cost that the registrant is liable to pay under or in relation to the *Pest Control Products Act*. Should there be an amount owing a request will be made to settle outstanding debt prior to processing the renewal. If the amount owing is not paid within 30 days of the request, PMRA may either refuse to consider applications by the registrant or cancel or amend the registration under section 23 of the *Pest Control Products Act*.

3.3 Taxes

Annual charges are exempt from taxes under the *Excise Tax Act*.

All fees identified in Schedules 1, 2, 3 and other fees described in Section 3.2 of this document are exempt from tax under the *Excise Tax Act* with the exception of the following.

Table 1 **Items not exempt from taxes under the *Excise Tax Act* (From Schedule 3 of the Regulations)**

Item	Type of Application	Fee (\$)
4	(a) Specification of maximum residue limit for a previously unexamined pest control product	125,461
4	(b) Specification of maximum residue limit for an unregistered use of a previously examined pest control product.	15,838

3.4 Fee Penalties

Consistent with the requirements of the *User Fees Act* section 5.1, when performance in a specific fiscal year does not meet the standards established, as outlined in the Management of Submissions Policy, by a percentage greater than 10%, a penalty equivalent to the amount by which the standard is missed, up to a 50% reduction in the fee will be applied to the relevant application types in the following calendar year.

4.0 Fee Form

A fee form has been developed to identify application components and applicable fees. The form consists of six (6) parts which correspond to sections relating to the three (3) fee Schedules (Part A, B and C), other fees (Part D), application for reduced fees (Part E) and payment of fees (Part F). Each part includes descriptions of the components and application types along with the relevant fees outlined in the *Fees and Charges Regulations*. Applicants must complete the appropriate row(s) and add the components together (if applicable), in order to determine the total fees for each application. Part A and Part E of the fee form must be completed for applications for reduced fees (refer to Section 5.0 of this guidance document).

The most recent fee form (form 6011) is available on Health Canada's website or by calling the Pest Management Information Service. The fee form will be updated as necessary to capture the annual fee adjustment as outlined under section 6 of the *Fees and Charges Regulations*. The most recent fee form and fees must accompany each application unless the application is exempt from all application fees. For a list of application types that are exempt from some or all application fees please refer to Section 2.0 of this guidance document.

4.1 Application Fee Structure

4.1.1 Calculating the Applicable Fee

Table 2 provides some examples of various application categories and types with the possible corresponding fees. The specific application categories are defined in the most recent version of the Management of Submissions Policy. This document is available on the Pesticides and Pest Management portion of Health Canada's website or by calling the Pest Management Information Service.

For some application types such as a major new use (Category A2.0) there is a range of data components that may be required depending on the use-site category (USC) being proposed. As a result, the fee will vary.

To assess fees in an efficient manner, the fee for each component, in Schedule 1 of the *Fees and Charges Regulations*, is based on the amount of effort required to review an average package of supporting data making up the component. Therefore, the same fee is charged for a component regardless of the amount of information (for example, the number of studies or the length of each study) contained in that component.

There will be either fewer or different components in Schedule 1 that apply to a Category B application in comparison to a Category A application thereby resulting in a lower fee for Category B applications.

For example, an application for a major new use of an active ingredient with supporting toxicology data would be subject to the Schedule 1 3(b) fee, whereas, a Category B application with an acute toxicology data package would be subject to the Schedule 1 3(c) fee.

For Category A and B applications, there will be one or more required data components with the corresponding Schedule 1 fee. The total fee is the sum of the fees for each fee outlined in column 2 of Schedule 1 plus the processing fee outlined under section 3 of the *Fees and Charges Regulations*.

Table 2 Examples of Possible Fee Components/Fees for Pest Control Product Applications

Application Category	Application Type	Possible Fee Components/ Fees under the <i>Fees and Charges Regulations</i>
Category A	New Technical Grade Active Ingredient (TGAI) – food use	Processing Fee, Items 1, (3a), 5, 7(a), 8(a) of Schedule 1
	New end-use product (EP) containing a new TGAI – food use	Processing Fee, Items 2, 3(c), 4(a), 5, 6, 7(a), 8(a), 9 of Schedule 1
	Major New Use – TGAI	Processing Fee, Items 1, 3(b), 4(b), 5, 7(b), 8(b) of Schedule 1
	URMUR	Same fee components as a new active ingredient or major new use of Schedule 1
	New microbial active ingredient — food use	Item 1 of Schedule 2
	New microbial active ingredient — food and non-food uses	Item 1 of Schedule 2 *
	Major New Use for a non-straight-chain semiochemical (food or non-food use)	Item 3 of Schedule 2
	New straight chain lepidopteran pheromone active ingredient - food or non-food uses	Item 7 of Schedule 2
Category B	Product chemistry amendment – EP	Processing fee, Item 2 of Schedule 1
	Category B streamline application	Processing fee, Item 9 of Schedule 1
	EP amendment application to add new pests to the label of a microbial product	Item 4 of Schedule 2

Application Category	Application Type	Possible Fee Components/ Fees under the Fees and Charges Regulations
Category C	TGAI or EP amendment to a microbial product — no data required	Item 6 of Schedule 2
	All Category C applications – except those subject to Schedule 2 fees	Processing fee
Category D	Import for Manufacture and Export Program (IMEP) – new registration	Item 3(a) of Schedule 3
	Master Copy or Private Label registration	Processing fee
	Registration renewal	Section 5
Category E	Research Authorization – major and minor crops	Item 1(a) of Schedule 3*
Category F	Notification applications	Section 4

* For Schedule 2 and 3 fees, if an applicant submits more than one application type as defined under Column 1 for the same pest control product at the same time, the total fee payable for that application is the highest of the relevant fees from Column 2.

Applicants may submit waiver rationales for specific studies or complete data components instead of submitting actual studies. An acceptable waiver request consists of a scientific rationale with supporting documentation (for example, literature search, surrogate data), all of which requires an assessment. Therefore, the applicable component fee will normally be charged for waiver requests.

Some documents that may be required in a complete data package should not be included in the calculation of application fees since they consist of a reorganization of information contained in other data components. These documents are summarized in Table 3. Therefore, if an application component listed on the left-hand column of Table 3 consists only of the PMRA data code (DACO) listed in the right-hand column, there is no fee for reviewing that application component.

Table 3 PMRA Data Codes Associated with No Applicable Fee for Review

Schedule 1 Application Component	Corresponding PMRA DACO	
Item 4(a), (b) or (c) Exposure Data	5.2	Use Description/Scenario (Application and Post Application)
Item 7(a), (b), or (c) Environmental Fate Data	8.2.1	Summary of Physicochemical Properties
	8.2.3.2	Hydrolysis
	8.4	Storage, Disposal and Decontamination
	8.4.1	Summary

In some situations an application may cross-reference or cite previously submitted data from another application. If the cross-referenced information requires an evaluation as part of the new

application, then the relevant application component fee will apply and should be calculated on the fee form. However, if an application component consists only of cross-referenced data that was previously submitted and evaluated and no further evaluation of that data is required, fees will not be charged for that application component.

5.0 Application for Reduced Application Fees

This section provides guidance on how to apply for a reduction of the fee payable under Schedule 1 for applications for new products only (in other words, a new pest control product registration number) as per section 8 of the *Fees and Charges Regulations*. Applications for amendments to existing products are not eligible for reduced fees. Application types listed in Schedules 2 and 3 of the *Fees and Charges Regulations* are not eligible for reduced fees.

Reduced fees are being offered to facilitate access to the Canadian market for low volume, niche products. The onus is on the applicant to supply sufficient evidence to support the application for the reduced fee.

5.1 Eligibility for Reduced Application Fees

To be eligible for a reduced fee, an applicant's anticipated gross revenues from sales in Canada of the pest control product(s) during the fee verification period must be less than 10 times the calculated application fee. Sales are defined as net sales of the product in Canada after all discounts (for example, volume discounts and promotional rebates).

5.1.1 Reduced Fee Threshold

The reduced fee threshold (RFT) is the amount of anticipated gross revenue from sales required for an application to qualify for a reduced fee. The reduced fee threshold is ten (10) times the calculated application fee.

$RFT = 10 \times \text{application fee (includes Schedule 1 fee + processing fee)}$

5.2 Estimating the Anticipated Gross Revenue

In order to establish eligibility for reduced application fees, the applicant must present information to support the anticipated gross revenue from sales of the pest control product in Canada during the fee verification period. The fee verification period is the period beginning on the date that the registered pest control product is first sold in Canada and ending three years after that date. The information should provide the expected market situation for the proposed product. The following is a list of minimum information that should be provided to the PMRA to support the calculation for anticipated gross revenue of the proposed product:

- i) detailed description of the product such as mode of action, formulation type, registration status in other countries, the proposed application rate(s) and frequency, use pattern(s), use site(s) and commodities/crops proposed;
- ii) target market(s) – including market description/definition, size (acreage, volume or other units) and demand for each proposed use;

- iii) comparison with similar competitive products – differences and similarities, advantages compared to other products registered for the same or similar uses (for example, pest/host combinations);
- iv) expected market share for each year of the 3 year fee verification period for all crops/commodities - including references for the values and any assumptions relied on for the calculations;
- v) expected average sale price per volume (for each submarket in the targeted group, if applicable) for each year of the fee verification period; and
- vi) anticipated gross revenue for the 3 years of the fee verification period.

If the product will be used on more than one crop/commodity each of the elements listed above must be described for each commodity in order to calculate an accurate estimation of anticipated gross revenue for the product.

Applicants should include valid references to support the information provided (for example, a Statistics Canada source for current acreage data, market information from Agriculture and Agri-Food Canada or historical data). Details should include what factors were used to determine the information and the method for arriving at the values presented in the fee reduction application package. Information should reflect appropriate container size and any dilution factors which may impact the calculations for the amount of product sold annually. Average values should be used for calculations and units should be converted to correspond for easy comparisons. Information for the reduced fee rationale should be presented in a manner that clearly indicates how the values were determined. Applicants may choose to present this information in a table or paragraph format.

A request for a reduction of fees and the accompanying information must be included with the application as a separate document under DACO 0.17.2 reduced fee rationale with confidential business information designation (CBI). The applicant must include a completed and signed fee form with the appropriate sections of the fee form completed to indicate a reduced fee is being requested.

5.3 Fee Payable When Reduced Application Fee Requested

As per subsection 8(5) of the *Fees and Charges Regulations*, the fee payable at the time the application is made in accordance with subsections 7(2) and (3) is the higher of the following amounts:

- (a) 10% of the anticipated gross revenue, and
- (b) 10% of the total fee payable

5.4 Calculation of Reduced Application Fees

For the purposes of calculating the reduced fee for applications, the anticipated gross revenue of all products that are registered based on the evaluation of the same data package must be added together. When calculating a reduced fee for an application for a pest control product containing a new active ingredient(s), the anticipated gross revenue and volume calculation will include the anticipated revenue from the net sales of all products containing the new active ingredient

registered during the fee verification period. These rules allow reduced application fees where the review costs are high compared to the potential benefit to the applicant (in other words, projected low product sales).

The application for reduced fees will be reviewed and verified during the screening stage of the completeness check. The applicant will be notified if the application for reduced fees has been accepted or rejected, if deficiencies are identified, or if any fee adjustments are necessary. The applicant will be notified of the fees that will be charged at each phase of the application review process.

Application fees are set at a maximum of 10% of the anticipated gross revenue from sales of all the products registered during the fee verification period. However, the fee reduction cannot reduce the fee payable to below 10% of the total application fee for each product.

Refer to Appendix II of this guide for examples of reduced fee calculations.

5.4.1 Recalculation of Reduced Fee

If a fee reduction was approved, the fee payable at the end of the fee verification period is the lesser of

- (a) The total application fee payable under Part 1 of the *Fees and Charges Regulations*, and
- (b) The higher of the following amounts:
 - i. 10% of the fee referred to in (a), and
 - ii. 10% of the actual gross revenue

5.5 Requirement of Certified Sales Records Following the Fee Verification Period

As per subsection 8(6) of the *Fees and Charges Regulations*, if the reduced fee request is granted, certified sales records must be submitted to the Accounts Receivable Unit at the end of the fee verification period. Certified sales records are prepared in accordance with generally accepted accounting principles and certified by the individual responsible for the registrant's or company's financial affairs. If the actual gross revenue stated in the certified sales records is greater than the anticipated gross revenue from sales, the balance payable will be due 60 days after the verification period ends.

As per subsection 8(8) of the *Fees and Charges Regulations*, if the records of sales establish that the amount that the registrant paid is more than the amount of the recalculated fee, the PMRA must repay the amount of overpayment to the registrant.

Under subsection 8(9) of the *Fees and Charges Regulations* the PMRA can require the registrant to submit sales records, which have been audited by a qualified independent auditor,¹ when the PMRA determines that certified sales records are not adequate to determine a person's actual gross revenue, for any product for which a reduced fee was granted. If there is any inconsistency between the certified records and the audited records, the fee payable is to be based on whichever records show the higher amount of sales in Canada, as per subsection 8(10) of the *Fees and Charges Regulations*.

When the sales reported in the certified sales record are lower than the sales reported in the audited sales record any interest on amounts owing to the Government of Canada as outlined in section 8.1 of this guide are payable to the Government of Canada.

6.0 Payment of Application Fees

6.1 Timing of Payment

For application fees where the amount due is \$2,500.00 or less, the total amount (that is, 100%) is payable at the time of application. This threshold is considered after any reduction of fees, if applicable.

There are three application types for which fees are over \$2,500.00 that also require payment in full at the time of application: research authorizations that fit within Item 1(a) or 1(b) of Schedule 3 and an application under the importation for manufacturing and export program within item 3(a) of Schedule 3.

For application fees, where the total fees are greater than \$2,500.00 after any applicable reduction, the timing of payment is as follows (as per subsection 7(3) of the *Fees and Charges Regulations*):

- 10% is payable at the time of application;
- 25% is payable upon receipt of an invoice issued when the application has been accepted for preliminary review; and
- 65% is payable upon receipt of an invoice issued when the application has been accepted for evaluation.

When the next step in the fee payment timing listed above applies, fees are payable before the next step of the examination of the application is started. The PMRA Accounts Receivable Unit will issue an invoice as the fees are due. If a fee instalment is not received the application will be kept on hold pending fee payment.

¹ The audit of sales records must follow Canadian auditing standards (CAS) – CPA professional conduct: Auditor independence – Harmonized Rules for Professional Conduct (Rule 204) or the most recent version thereof and be performed by a qualified independent auditor. A qualified independent auditor must be a member in good standing with the Chartered Professional Accountants of Canada or the American Institute of Chartered Professional Accountants (United States), the Association of Authorized Public Accountants (United Kingdom) or the International Institutes of Accountants as approved by Health Canada.

Though applicants have the flexibility to pay application fees in full at the time of application, during the fourth quarter (January – March) of each fiscal year, the PMRA encourages payments in increments, upon receipt of an invoice, to ensure that revenue is applied to the services that applicants benefit from during a specific fiscal year.

6.2 Withdrawn and Denied Applications

If the applicant submits a written request to withdraw an application or an application is denied by the PMRA, the required fees paid up to the point of withdrawal/denial will not be refunded.

7.0 Annual Charge for all Registered Pest Control Products

An annual charge of 4% of actual gross revenue will be applied to each registered product with a minimum payment of \$100 and a maximum of \$3,600 per product. All registered products including technical grade active ingredients (TGAI), import for manufacturing and export program (IMEPs), private label products and master copies must pay the annual charge. Actual gross revenues are defined as the total dollar sales of the product in Canada after all discounts (for example, volume discounts and promotional rebates).

See Appendix III for examples of annual charge calculation scenarios.

7.1 Timing of Payment

Under paragraph 9(2)(b) of the *Fees and Charges Regulations* four (4) invoices will be issued by the PMRA and sent in one mailing to each registrant for products registered in that registrant's name on April 1 of each year. Upon receipt of the invoices, annual charges can be paid in full or in four equal instalments due on May 30, August 28, November 26, and February 24.

7.2 Notice of Request for Audited Sales Records

If the PMRA determines, based on available information, that the certified sales records required under subsection 9(3) of the *Fees and Charges Regulations*, as a condition for receiving a reduced annual charge, are not adequate to determine the registrant's actual gross revenue, the PMRA may require (under subsection 9(4) of the *Fees and Charges Regulations*) that the registrant provide records of the sales in Canada that have been audited by a qualified independent auditor.

For any product for which a reduced annual charge is requested if the audited sales records are not provided to the PMRA, the full annual charge per product will be payable. If the sales reported on the audited sales record are higher than the sales reported on the certified sales record, the charge payable will be based on the audited sales record.

Interest on amounts owing to the Government of Canada as outlined in Section 8.1 of this guide may be payable to the Government of Canada where the sales reported in the certified sales record are lower than the sales reported in the audited sales record.

7.3 Registration Being Transferred

Registrants in the process of transferring a product to another registrant, for whom the transfer has not been completed as of April 1 of a given year, are responsible for paying the annual charge for that product.

7.4 Discontinuation of Registration

The annual charge remains payable for the product as long as the product remains registered, regardless of whether the registrant has discontinued sale of the product. If a registrant wishes to discontinue the registration of a product to avoid paying the annual charge, the request to discontinue the product must be received by the PMRA prior to April 1 each year, and the registrant must not have any stock remaining.

If there is stock remaining in the marketplace and the registrant wishes to discontinue the registration immediately, the registrant will have to provide a plan along with the request to discontinue the registration of the product for approval by the PMRA, on recalling and disposing of unused stock.

Alternatively, the PMRA may process the discontinuation but it will not take effect until the year in which the registrant has estimated that all stock in the marketplace will be exhausted. The registrant will be assessed annual charges for this interim period; however, the registrant may qualify for a reduced annual charge based on sales for that product.

It is not possible under the process for payment of the annual charge to amend the registration of products. All such proposed changes must be submitted via an application for new or amended registration or, if applicable, through the notification application process.

Should a registrant have an outstanding balance for past annual charges and submits certified sales records to pay a reduced fee on a registered product, efforts will be made, consistent with Health Canada Collection Administration Procedures, to settle outstanding debt prior to processing new annual charge reductions. If the amount owing is not paid within 30 days of attempts to collect the outstanding balance PMRA may either refuse to consider applications by the registrant or may cancel or amend a registration under section 23 of the *Pest Control Products Act*.

8.0 Interest and Administrative Charges

Interest and administrative charges will be assessed as outlined below pursuant to the Interest and Administrative Charges Regulations.

8.1 Interest

Where an amount is owing to the Government of Canada, interest calculated and compounded monthly at the average bank rate plus 3% is payable on that amount and accrues during the period beginning on the due date and ending on the day when payment is received by the Government of Canada.

“Due Date” means the due date specified in a demand for payment. Where no date has been specified or included in the demand for payment, the due date is 30 days after the day on which a

demand for payment is issued or any day on which payment is to be made in accordance with the applicable Act of Parliament, regulation, order, contract or arrangement.

8.2 Administrative Charges for Dishonoured Instruments

Where an instrument tendered in payment or settlement of an amount is, for any reason, dishonoured, an administrative charge of \$15.00 is payable by the debtor.

Where a payment is made by the PMRA to a financial institution in order to reimburse that institution for an amount initially credited to the Receiver General on the basis of a dishonoured instrument, an administrative charge of \$10.00 is payable by the debtor.

Where a financial institution charges an amount to the PMRA for monitoring the account of a debtor who has tendered a dishonoured instrument and for subsequently certifying or clearing that dishonoured instrument, an administrative charge in that amount is payable by the debtor, in addition to the charge referred to in the first paragraph of this section.

9.0 Methods of Payment

All payments must be made in Canadian (CAD) funds. The PMRA is not responsible for transaction fees. Failure to pay the full amount outstanding will result in a balance owing on your account.

Contact the PMRA Accounts Receivable Unit for any payment questions you may have.

PMRA Accounts Receivable Unit

Phone: (613)-736-3530 or Toll Free at 1-800-267-6315

Fax: (613)-736-3620

E-mail: pmra.receivable-receivable.arla@hc-sc.gc.ca

When submitting an application, the selected payment method and payment contact/authorization information is to be included on the "Payment of Fees" section of the Fee Form.

The PMRA accepts the following methods of payment:

- **Online Banking:** This payment option is not available to first time applicants. The PMRA is registered with all major Canadian Banks to receive payments through online banking. Your 10 digit Client ID, as found on your invoice, is required.

Online Banking Payment process:

- Log in to your online bank account
- Click Pay Bills and select "Add a bill Payee"
- Type Pest Management Regulatory Agency (PMRA) in the Name of the Organization (Payee) field* and click OK
- Type your 10 digit Client ID Number (from you invoice) into the Account Number field

- Click "OK" or "Submit"

*The payee name may differ across various financial institutions. Other branches of Health Canada may appear as a Payee option. Ensure "PMRA" or "Pest Management Regulatory Agency" appears in the Payee name.

- **Credit Card:** Applicants can pay by a credit card through one-time payment or through a number retained on file at the PMRA (preference to be indicated on the Fee Form). Credit card payments with Visa, MasterCard or American Express are accepted.

The following information will be required to pay by credit card:

- Cardholder's full card number;
- Cardholder's name, address and telephone number;
- Card Expiry date

The PMRA Accounts Receivable Unit will refer to the Fee Form for applicant contact information when processing payment. Note that the PMRA will not accept Credit Card information by e-mail.

- **Wire Transfers:** Contact the PMRA Accounts Receivables Unit for information to complete a wire transfer. Wires must be completed in Canadian Funds. Refer to Section 1.0 for the PMRA's Accounts Receivable Unit contact information.

Required information:

Bank Name	Scotiabank Toronto Business Service Centre 20 King Street West, Toronto Ontario, Canada, M5H 3R3
SWIFT	NOSCCATT
Bank Number:	002
Canadian Routing	//CC000247696
Code:	47696
Transit Number:	
Beneficiary Name:	Receiver General for Canada
Beneficiary Account	47696-1159712
Number:	
Beneficiary Account	Receiver General for Canada
Address:	Portage III, 15A2, 11 Laurier Street Gatineau, Quebec K1A 0S5
Description Field:	022-22736

Note that the wire standards used in Canada offer 4 lines of description fields, each with a maximum of 35 characters. Please include the following information:

Customer number and Client ID: (3 letters example – AAA)

Invoice number: 009-

Name of Company:

Registration No:

- Cheque: Payments made by cheque should be made payable to the "Receiver General for Canada" and, as stated on the invoice, payment should be sent to:

Pest Management Regulatory Agency Accounts Receivable
5th floor, Sir Charles Tupper Bldg. A.L.6605C1
2720 Riverside Drive Ottawa, Ontario K1A 0K9

- Using Existing Credit: Overpayment of fees will be credited to your account. You may request that we apply your credit balance to payment/partial payment of future fees.

10.0 Refunds

A written request from an authorized person is required for a refund of a credit balance. Contact the PMRA Accounts Receivable Unit for questions regarding refunds.

PMRA Accounts Receivable Unit - 6605C1
2720 Promenade Riverside Drive
Ottawa ON K1A 0K9

Phone: (613)-736-3530 or Toll Free at 1-800-267-6315

Fax: (613)-736-3620

E-mail: pmra.receivable-receivable.arla@hc-sc.gc.ca

11.0 Complaint Mechanism and Appeals Procedure

The applicant or registrant may appeal decisions regarding the application of the *Fees and Charges Regulations*. The first step which should be taken by the applicant is to contact the administrative coordinator for the application. The administrative coordinator will assist the applicant in using the appeal/complaint process and will provide the status of ongoing appeals/complaints.

The appeal must be received within 30 calendar days following issuance of the invoice. All appeals must be received in writing, by mail or email. For application fees, the appeal or complaint should be directed to the Director of the Submission and Information Management Division. The Director of the Submission and Information Management Division will review the decision in question and will send the appellant a reply which will include the decision on the appeal and the rationale for the decision within 15 calendar days after receipt of the appeal. The review of the application will not proceed until the dispute is resolved. For annual charges, the appeal or complaint should be directed to the PMRA Accounts Receivable Unit.

Appendix I List of Exemptions

Listed below are substances that if they are an active ingredient in an application for a certificate of registration of a pest control product, the pest control product will be exempt from application fees except for the processing fee. This exemption is pursuant to subsection 1(d) of the Fees and Charges Regulations. For applications for registration of a pest control product containing more than one active ingredient, all of the active ingredients must be eligible for the exemption in order for the application to be exempt from the application fees.

- 1) An organism that is not a microbial agent
- 2) Substances, regardless of use pattern, if they have been regulated under the *Food and Drugs Regulations* as:
 - a) a food additive that is set out in a list in accordance with a marketing authorization issued by the Minister under subsection 30.3(1) of the Food and Drugs Act
 - b) a nutritive substance that is used, recognized or commonly sold as food or as an ingredient of food
Examples of these substances may include:
 - i) garlic extract and garlic oil
 - ii) sesame
 - iii) soybean oil
 - iv) rosemary
 - v) corn oil
 - vi) thyme and thyme oil
 - c) vitamin, mineral nutrient or amino acid
 - d) a flavouring preparation, natural extractive, oleoresin, seasoning or spice
 - e) a food packaging material or any substance of which such a material is composed
 - f) a drug for veterinary use in animals that may be used as food for human consumption
Examples of these substances may include:
 - i) glycerine
 - ii) menthol
 - iii) mineral oil

Appendix II Examples of Reduced Fee Calculations

(A) Application for a new end-use product (EP) with low projected sales.

An application for a new EP product is made. The calculated application fee is \$71,712. Therefore the reduced fee cannot be lower than \$7,171 (10% of the total application fee). The anticipated gross revenue of the product during the fee verification period is \$385,000.

The reduced fee threshold (RFT) is $10 \times \$71,712 = \$717,120$. Since the reduced fee threshold is greater than \$385,000, the application qualifies for a reduced fee. The fee payable will be equal to 10% of the anticipated gross revenue (\$38,500) as long as that amount is not less than 10% of the full application fee. In this case, \$38,500 is not less than the minimum \$7,171 therefore the application does qualify for the reduced fee and the fee payable is \$38,500.

Table 4 Application for a new end-use product (EP) with low projected sales example calculation

Full Application Fee	3 year anticipated gross revenue	Fee Payable
\$71,712	\$385,000	\$38,500
Minimum Reduced Fee Calculation = \$7,171		
RFT = \$717,120	10% of gross revenue = \$38,500	

(B) Application for a new end-use product (EP) with low projected sales.

An application of a new EP product is made. The calculated application fee is \$69,247. Therefore the reduced fee cannot be lower than \$6,925 (10% of the full fees). The anticipated gross revenue of the product during the fee verification period is \$58,500.

The reduced fee threshold (RFT) is $10 \times \$69,247 = \$692,470$. Since the reduced fee threshold is greater than \$58,500 the application qualifies for a reduced fee. The fee payable will be equal to 10% of the anticipated gross revenue (\$5,850) as long as that amount is not less than 10% of the full application fees. In this case, \$5,850 is less than the minimum \$6,925 therefore the fee payable is \$6,925.

Table 5 Application for a new end-use product (EP) with low projected sales example calculation

Full Application Fee	3 year anticipated gross revenue	Fee Payable
\$69,247	\$58,500	\$6,925
Minimum Reduced Fee Calculation = \$6,925		
RFT = \$692,470	10% of gross revenue = \$5,850	

(C) Applications for a new technical grade active ingredient (TGAI) and three (3) associated end-use products (EPs).

Applications for a new technical grade active ingredient (TGAI) and three (3) new associated end-use products are made. The application fees, RFT and anticipated gross revenue for each application are outlined below.

Sales for a new TGAI: For an application to register a new TGAI, the revenue from sales is considered to include the gross revenue from sales of all products, containing the new TGAI, registered during the fee verification period.

Since all applications for EPs are received at the same time and share data components, the sales of all EPs must be added together when determining the total anticipated gross revenue during the fee verification period.

Table 6 Applications for a new technical grade active ingredient (TGAI) and three (3) associated end-use products (EPs)

Application	Full Application Fee	RFT	Minimum Reduced Fee Calculation (10% of Full Application Fee)	3 year anticipated gross revenue	Fee Payable**
TGAI	\$190,696	\$1,906,960	\$19,070	\$0.00*	\$100,000
EP1	\$120,981	\$1,209,810	\$12,098	\$500,000	\$100,000
EP2	\$13,464	\$134,640	\$1,346	\$400,000	\$13,464
EP3	\$1,133	\$11,330	\$113	\$100,000	\$1,133
Totals	\$326,274			\$1,000,000	\$214,597
			10% of gross revenue	\$100,000	

* In some cases there are no Canadian sales of the TGAI (because the EPs are imported into Canada or the TGAI will be used only in the applicant's own products (i.e., no external sales)

** The lesser of the full application fee or 10% of the sales of all of the products during the fee verification period

For the TGAI and EP1 applications, the RFTs are greater than the total anticipated gross revenue for all products therefore these applications qualify for a reduced fee. However, the RFT for EP2 and EP3 are not greater than the total anticipated gross revenue for all products therefore the fee payable for these applications is the full application fee, not a reduced fee.

For the TGAI, the fee payable is equal to 10% of the total anticipated gross revenue for all products (\$100,000) as long as that amount is not less than 10% of the full fees for that application. In this case, \$100,000 is more than \$19,070 therefore the TGAI application qualifies for a reduced fee and the fee payable is \$100,000.

Similarly, the fee payable for EP1 is equal to 10% of the total anticipated gross revenue for all products (\$100,000) as long as that amount is not less than 10% of the full fees for that application. Since \$100,000 is more than \$12,098 the EP1 application qualifies for a reduced fee and the fee payable is \$100,000.

(D) Applications for three (3) new end-use products (EP) applied for at the same time and based on substantially the same data package.

Applications for three (3) new associated end-use products (EPs) are made. The application fees, RFT and anticipated gross revenue for each application are outlined below.

Since all applications for EPs are received at the same time and share data components, the sales of all EPs must be added together when determining the total anticipated gross revenue during the fee verification period.

Table 7 Applications for three (3) new end-use products (EP) applied for at the same time and based on substantially the same data package

Application	Full Application Fee	RFT	Minimum Reduced Fee Calculation (10% of Full Application Fee)	3 year anticipated gross revenue	Fee Payable*
EP1	\$41,019	\$410,190	\$4,102	\$100,000	\$30,000
EP2	\$4,095	\$40,950	\$410	\$150,000	\$4,095
EP3	\$1,133	\$11,330	\$113	\$50,000	\$1,133
Totals	\$46,247			\$300,000	\$35,228
			10% of gross revenue	\$30,000	

* The lesser of the full application fee or 10% of the sales of all of the products during the fee verification period

For the EP1 application, the RFT is greater than the total anticipated gross revenue for all products therefore this application qualifies for a reduced fee. However, the RFT for EP2 and EP3 are not greater than the total anticipated gross revenue for all products therefore the fee payable for these applications is the full application fee, not a reduced fee.

For the EP1, the fee payable is equal to 10% of the total anticipated gross revenue for all products (\$30,000) as long as that amount is not less than 10% of the full fees for that application. In this case, \$30,000 is more than \$4,102 therefore the fee payable is \$30,000.

Appendix III Annual Charges Calculation Examples

Listed below are example scenarios relating to the calculation of annual charges.

Example 1: The registrant has a product with \$1 million in sales in the previous fiscal year. The company pays an annual charge of \$3,600.

Example 2: The registrant has a product with \$50,000.00 in sales in the previous fiscal year. The company pays an annual charge of 4% of \$50,000.00 = \$2,000.

Example 3: The registrant has a product with \$2,000.00 in sales in the previous fiscal year. The company pays an annual charge of \$100 because 4% of \$2,000 = \$80 (which is below the minimum charge of \$100).

Example 4: The registrant has a product that is not manufactured in Canada and has zero sales. The company pays the minimum annual charge of \$100.

Example 5: The registrant has three products with sales of \$1 million, \$50,000.00 and \$2,000 respectively in the previous fiscal year. The company pays annual charges of $\$3,600 + \$2,000 + \$100 = \$5,700$.

Example 6: The registrant has five products with sales greater than \$1 million in the previous fiscal year. The registrant pays annual charges totaling $5 \times \$3,600 = \$18,000$.